REMARKS

With entry of this Amendment, claims 1, 6-9, 39, and 40 are pending. Applicants have canceled claims 4 and 5 without prejudice or disclaimer of the subject matter of those claims. Applicants amended claim 1 to recite a "composition for applying to the skin wherein the composition contains 1 to 10% by weight of the purine nucleic acid-substance, and 0.0001 to 10% by weight of the pyrimidine nucleic acid-substance per total weight of the composition." Applicants amended claim 39 to recite a "skin treatment formulation." Applicants also added new claim 40. Support for the amendments to claims 1 and 39 may be found in the specification at, for example, page 17, line 4; page 14, line 6; page 11, lines 20-22; page 17, lines 7-16; and page 25, line 23 to page 26, line 7. Support for new claim 40 can be found in the original claims, as well as in the specification at page 14, line 6, and page 16, lines 19-25. Applicants believe that these amendments do not introduce new matter.

Applicants acknowledge with appreciation the Office's withdrawal of the prior rejections under 35 U.S.C. §§ 102(b) and 103(a). The Office maintains the rejection based on alleged obvious-type double patenting, but has modified it slightly to account for Applicants' amendments filed on January 8, 2009. The Office newly rejects claims 1 and 4-9 under 35 U.S.C. § 102(b) and claim 39 under 35 U.S.C. §§ 112, first and second paragraphs, and 103(a). Applicants address these rejections below.

Rejection Based On Obviousness-Type Double Patenting

The Office maintained its provisional rejection of claims 4-9 under the judicially created doctrine of obviousness-type double patenting in light of claims 1 and 3-15 of copending U.S. Application No. 10/574,696 (the '696 application) in view of Collins *et al.* (U.S. Patent No. 6,203,805 B1). Office Action, p. 4. The Office alleges that the respective sets of claims of the instant application and the '696 application are drawn to a method for promoting collagen production comprising applying to the skin a composition comprising at least one purine nucleic acid-related substance selected from adenosine monophosphate or salts thereof, and at least one pyrimidine nucleic acid-related substance selected from uridine monophosphate and salts thereof. *Id.* at 5. The Office acknowledges that the copending claims of the '696 application do not teach that the compositions additionally comprise an additive as claimed in the instant invention. *Id.* Therefore, the Office relies on Collins for allegedly teaching topical compositions comprising whey protein and vitamins for enhancing the production of collagen and improving the resiliency of skin. *Id.*

According to the Office, "[i]t would have been obvious to one of ordinary skill in the art to add one of the well-known useful active additives (i.e. anti-inflammatory agents, humectants, etc.) taught by Collins to the topical composition comprising at least one purine nucleic acid-related substance selected from adenosine monophosphate or salts thereof, and at least one pyrimidine nucleic acid-related substance selected from uridine monophosphate and salts thereof used in the method of the co-pending claims." *Id*.

Applicants address this rejection with respect to claims 1 and 6-9, which are still pending. Solely to expedite prosecution, and without acquiescing in the rejection, Applicants attach a terminal disclaimer. In view of this Terminal Disclaimer, the double patenting rejection is most and should be withdrawn.

Rejections Under 35 U.S.C. § 112

Claim 39 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *Id.* at 6. According to the Office, "[c]laim 39 is directed to two separate compositions, each of which comprises at least one additive." *Id.* at 7. The office further alleges that "the specification allegedly fails to provide adequate support for a skin treatment comprising two separate compositions, each containing an additive." *Id.* Instead, the Office alleges that the specification "discloses adenosine monophosphate (AMP) or salt thereof, uridine monophosphate (UMP) or salt thereof, and additives in a **single** composition." *Id.* (Emphasis added.) Applicants disagree.

The specification describes two separate compositions that can be applied successively in any order; the first composition containing a purine nucleic acid-related substance, and the second composition containing a pyrimidine nucleic acid-related substance. Particular support for this teaching can be found in the specification at page 25, line 23 to page 26, line 5. Page 26, lines 1-5 instructs that "a purine nucleic acid-related substance or a composition containing the same and a pyrimidine nucleic acid-related substance or a composition containing the same may be successively applied to the skin . . . in any desired order." This passage in the specification expresses an embodiment in which each composition *contains* a purine nucleic acid-

related substance or a pyrimidine nucleic acid-related substance, demonstrating that the inventors contemplated that other ingredients, such as the additives recited in claim 39, could be present in each composition. Thus, the specification supports claim 39.

Accordingly, Applicants request that the rejection of claim 39 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim 39 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. *Id.* at 7. More specifically, the Office asserts that it is unclear whether the phrase "skin treatment" "is directed solely to a composition or directed to a method."

Applicants have amended claim 39 to recite a "skin treatment formulation." Thus, Applicants respectfully submit that amended claim 39 speaks to a composition and not a method. Accordingly, the rejection of claim 39 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 1 and 4-9 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gil *et al.* (U.S. Patent 5,066,500) as evidenced by Zimmerman *et al.* (published U.S. Application 2002/0141955 A1). *Id.* at 8. According to the Office, Gil teaches non-milk based infant formulas and nutritionally balanced diet formulations comprising CMP, GMP, IMP, AMP and UMP, and allegedly teaches a formulation including ascorbyl palmitate. *Id.* Relying on Zimmerman, the Office contends that ascorbyl palmitate is a skin whitening agent, attempting to show that the claimed

ascorbyl palmitate is a skin whitening agent, attempting to show that the claimed invention is anticipated when a whitener is chosen as an additive. *Id.* at 7-8. Applicants address this rejection with respect to claims 1 and 6-9, which are still pending.

To establish anticipation under 35 U.S.C. § 102, the Office must establish that a reference teaches, either expressly or inherently, each and every element of a claim. See M.P.E.P. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). A rejection under § 102 is proper only when the claimed subject matter is <u>identically</u> described or disclosed in the prior art. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (emphasis added).

In the instant case, the Office's 35 U.S.C § 102(b) rejection is improper, at least because Gil does not teach or suggest each and every element of the pending claims. For example, Gil discloses a non-milk based infant formula which may contain 1-300 mg/100 g (i.e., 0.001-0.3 wt%) of adenosine phosphate as the widest possible range for the amount of this component. Gil at col 5, II. 35-40. Thus, Gil does not describe a composition containing "1%-10 % by weight of [a] purine nucleic acid substance." In other words, the recited concentration range of a purine nucleic acid substance in independent claim 1 does not overlap the concentration range of adenosine phosphate taught by Gil. Thus, Gil does not teach or suggest each and every element of independent claim 1 and therefore cannot anticipate claims 1 and 6-9. Applicants therefore submit that the 35 U.S.C. § 102(b) rejection in view of Gil as evidenced by Zimmerman should be withdrawn.

Rejection Under 35 U.S.C. § 103

Claim 39 stands rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Gil *et al.* (U.S. Patent 5,066,500) as evidenced by Zimmerman *et al.* (published U.S. Application 2002/0141955 A1). *Id.* at 9. The Office applies Gil and Zimmerman as discussed *supra* with regards to claims 1 and 4-9, but notes that neither reference teaches two separate compositions each containing an additive. *Id.* at 10.

Nonetheless, the Office concludes, without providing a basis for its conclusion, that "the arrangement of the components in the composition into two separate compositions is . . . obvious." *Id.* The Office also notes that if the additive in the two compositions is the same, then there would be no substantial difference between the components in the single composition and the components in the treatment. *Id.* Applicants respectfully traverse.

As the Office acknowledges, neither Gil nor Zimmerman do not teach a formulation comprising two separate compositions, let alone a first composition that contains "at least one purine nucleic acid-related substance chosen from adenosine monophosphate and a salt thereof" and a second composition that contains "at least one pyrimidine nucleic acid-related substance chosen from uridine monophosphate and a salt thereof." The formulations of Gil contain several ingredients. For example, the formulation of Example VII lists 46 different ingredients. However, nothing in Gil instructs or suggests to one of ordinary skill in the art that of those 46 ingredients, the adenosine or its salt and the uridine and its salt should in particular be split into two separate compositions. Zimmerman also fails to provide such guidance to one of ordinary skill in the art because that reference focuses on methods for slowing the

decomposition of compositions containing skin whiteners. Moreover, separating the nucleic acid-related substances of the invention into two separate compositions is counter-intuitive because the application of two compositions to the skin is more burdensome than the application of just one and the manufacturing of two separate compositions is also more expensive and burdensome.

The Supreme Court in KSR v. Teleflex explained that "[t]o facilitate review, this analysis [of whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue] should be made explicit." KSR Int 'I Co. v. Teleflex Inc., et al., 127 S. Ct. 1727, 1741 (2007) (emphasis added) (citing In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")). Here, the Office has made the conclusory statement that "the arrangement of the components in the composition into two separate compositions is deemed obvious absence [sic] a showing of unexpected results," without adding further explanation. Id. Thus, Applicants respectfully submit that the Office has not provided a reason why an ordinarily skilled artisan would have separated the nucleic acid-related substances of the invention into two separate compositions. Indeed, the Office "bears the initial burden of factually supporting any prima facie conclusion of obviousness." M.P.E.P. § 2142. Applicants therefore request that the Office withdraw the rejection of claim 39 under 35 U.S.C. § 103(a).

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of claims 1, 6-9, 39 and 40.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: July 30, 2009

Maryann T. Puglielli Reg. No. 52,138 (202) 408-6054